K011277

10. 510(k) Summary of Safety and Effectiveness

JUN 2 6 2001

Submitter

S & C Polymer GmbH
Robert-Bosch-Strasse 5
D-25335 Elmshorn
(0049) (0) 4121-4830 (Phone)
(0049) (0) 4121-87221 (Fax)
Dr. Jürgen Engelbrecht (Contact Person)

Date Summary Prepared: April 2001

Device Name:

- Trade Name: Hard Reline
- Common Name: Denture Relining Material
- Classification Name (per 21 CFR § 872.3760): Resin, Denture, Relining, Repairing, Rebasing

Devices for which Substantial Equivalence is Claimed:

VOCO, *Ufi Gel hard*

Device Description:

Hard relining material for relining and rebasing dentures. Hard Reline contains a cartridge and an adhesive for automixing application of the rebasing material.

Intended Use of the Device:

Cold-curing permanent hard relining material for denture relinings.

Substantial Equivalence:

The products are substantially equivalent to other legally marketed devices in the United States. The Material marketed by VOCO functions in a manner similar to and is intended for the same use as the product manufactured by S & C Polymer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 6 2001

Mr. Jurgen Engelbrecht
President
S & C Polymer GMBH
Robert-Bosch-Strasse 5
Elmshorn,
GERMANY

Re: K011277
Trade/Device Name: HARD Reline
Regulation Number: 872.3760
Regulatory Class: II
Product Code: EBI
Dated: June 6, 2001
Received: June 15, 2001

Dear Mr. Engelbrecht:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011277

9. Statement of Indications for Use

510(k) Number (if known):

Device Name: Hard-Reline

Indications for Use: Content: Relining Material "Hard Line" and the adhesive "Hard Prime".

Hard Reline is intended for use as a permanent hard relining material to restore the functions of partial and complete dentures and lengthening of denture margins.

Hard Line: Cold-curing permanent hard relining material for denture relinings.

Hard Prime: Priming agent for dentures and the hard relining material Hard Line.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K011277

Prescription Use: ✓ or Over-The-Counter Use: